K123248

510(k) SUMMARY

AvanTech, Inc.'s CPR RsQ Assist

DEC 10 2013

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

AvanTech, Inc.
559 Audubon Blvd., Apt. 301
Naples, Florida 34110
Phone: 1-877-598-1234
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Contact Person: Joseph J. Hanson, President

Date Prepared: December 3, 2013

Name of Device and Name/Address of Sponsor

CPR RsQ Assist

Joseph J. Hanson
559 Audubon Blvd., Apt. 301
Naples, Florida 34110

Common or Usual Name

Cardiopulmonary Resuscitation Aid

Classification Name

21 CFR 870.5200 Cardiopulmonary Resuscitation Aid

Predicate Devices

Bio-Detek, Inc.'s PocketCPR (K071321)

Elcare Innovations, Inc.'s The Grip (K010526)

Intended Use / Indications for Use

The CPR RsQ Assist is intended to assist the rescuer in performing chest compressions at the recommended American Heart Association (AHA) rate of 100 compressions/minute on a victim 8 years or older.

Technological Characteristics

The CPR RsQ Assist consists of a rigid plastic top with an integrated plastic support collar, a flexible plastic bellows filled with foam, and a removable silicone base platform. LED lights and a speaker component provide visual and audio cues, respectively, to the user during manual CPR compressions.

The CPR RsQ Assist is provided non-sterile.

Performance Data

In support of this 510(k) Premarket Notification, AvanTech, Inc. has conducted bench testing to demonstrate that the CPR RsQ Assist provides adequate mechanical strength and performs appropriately for its intended use. The company has conducted the following tests:

- Mechanical test to failure
- Structural integrity "drop" test
- Simulated use on conventional CPR manikin
  - Chest displacement depth and rate
  - Chest compression force
- Low battery indicator
- Electromagnetic compatibility testing according to IEC 60601-1-2
- Electromagnetic Compatibility immunity testing according to IEC 61000-4-2 (Electrostatic Discharge Immunity Test) and IEC 61000-4-3 (Radiated, Radio-Frequency Electromagnetic Field Immunity Test)

Performance testing confirmed that the CPR RsQ Assist functions as intended and meets all of its performance specifications. In addition, the biocompatibility of the patient-contacting device material was established based on testing performed according to ISO 10993-1.

Substantial Equivalence

The CPR RsQ Assist is as safe and effective as Bio-Detek, Inc.'s PocketCPR (K071321) and Elcare Innovations, Inc.'s The Grip (K010526). The CPR RsQ Assist has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the CPR RsQ Assist and its predicate devices raise no new types of safety or effectiveness questions. Performance data demonstrate that the CPR RsQ Assist is safe and effective

to perform its intended use to assist the rescuer in performing chest compressions at the recommended AHA rate of 100 compressions per minute on a victim 8 years or older. Thus, the CPR RsQ Assist is substantially equivalent to its predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 10, 2013

Avantech, Inc.
c/o Hogan Lovells US LLP
Attn: Steven B. Datlof, M.D., J.D.
1835 Market Street, 29th Floor
Philadelphia, PA 19103

Re: K123248
Trade Name: CPR RsQ Assist Device
Regulation Number: 21 CFR 870.5200
Regulation Name: External Cardiac Compressor
Regulatory Class: III (Three)
Product Code: LIX
Dated: October 1, 2013
Received: October 1, 2013

Dear Dr. Datlof:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123248

Device Name: CPR RsQ Assist

Indications for Use: The CPR RsQ Assist is intended to assist the rescuer in performing chest compressions at the recommended American Heart Association (AHA) rate of 100 compressions/minute on a victim 8 years or older.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use___X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)